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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,423	03/10/2005	Albert Duranton	122005	2517

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,423	DURANTON ET AL.	
	Examiner	Art Unit	
	GINA C. YU	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8-15, 19-43* is/are pending in the application.

4a) Of the above claim(s) *14,22-25,27-38,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-13, 15, 19-21, 26, 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on May 28, 2009. Claims 1-6, 8-15, 19-43 are pending. The claim rejections made under 35 U.S.C. § 112, first paragraph, are withdrawn in view of applicant's claim amendment. The claim rejection made under 35 U.S.C. § 103 (a) is maintained for the reasons of record, with modification to address the applicant's claim amendment. See Election/Restriction below.

Election/Restrictions

The amended claim 12 is now directed to a species that is distinct from the originally an invention that is distinct from the invention originally claimed for the following reasons: During telephone interview on October 17, 2007 with applicant's then-representative Samuel Dagremond, the examiner at that time has agreed to withdraw restriction between groups I (claims 1-15) and VI (claims 39-41) as the inventions were similar, and applicant's representative has elected polyphenols among other supplement agents within instant claims 39-41. See applicant's remarks filed on November 13, 2007; interview summary, paper number 20080122. Claim 12 originally had two supplement agents polyphenols and fatty acids, however, the May 28, 2009 amendment now requires the supplement agent be at least one fatty acid. Since applicant has successfully persuaded the examiner that inventions of claims 1-15 and 39-41 are similar and elected polyphenols for claims 39-41, it is viewed that applicant implicitly has agreed to elect the same species for claims 1-15 as well, thereby leaving

the fatty acid of claim 12 as a non-elected species. Accordingly, claim 12 is withdrawn from consideration as being directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-11, 13, 15, 19, 20, 21, 26, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada et al. (JP 2002-097116, Machine translation) in view of Kung (US 5639785) and McCarty (US 5582839).

Hamada teaches that taurine acts as a cellular activator for regulating hair cells and discloses hair-stimulating compositions for topical application.

Hamada fails to teach oral administration of taurine.

Kung teaches pharmaceutical compositions of isoflavanoid derivatives (polyphenols) for the treatment of male pattern baldness and alopecia areata, and in promoting the conversion of gray hair to the original pigment in hair follicles. See abstract. The reference indicates that it is well known and conventional practice in pharmaceutical art to administer active compounds in various routes via oral and topical formulations, among others. See col. 4, lines 31-46. Specific types of formulations including tablets, capsules, powders, soft gels, solutions, emulsions, creams or ointments are mentioned. The reference teaches that both topical and oral administration of Minoxidil and daidzein treat baldness. See col. 1, lines 16-29. As for the dosage and the effective amount of daidzein, the reference indicates that the quantity will vary depending on the patient and the mode of administration. The

reference indicates that from about 0.001-20 mg/kg of body weight of the patient per day may be used to achieve the desired effect. See col. 4, lines 46-56.

While Hamada and Kung do not specifically disclose orally administrable form of taurine, oral formulation of a highly soluble mineral salt of taurine, such as magnesium taurate, is already well-known in pharmaceutical art. See McCarty, col. 3, lines 5-23.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teaching of Hamada by formulating orally administrable compositions as motivated by Kung because 1) Hamada teaches using taurine to treat alopecia; 2) Kung teaches that designing both topical and oral formulations of anti-alopecia compounds such as Minoxidil and diadzien is well known in the art; and 3) McCarty teaches that oral administration of taurine salt already has been in practice.

As for the suitable amount of taurine in the composition, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, prior arts provides general condition of making the drug since Hamada teaches a suitable amount of taurine in topical formulation in treating alopecia and Kung and McCarty teach oral formulation. Given these teachings, discovering an optimal weight of the active ingredient would have been within the skill of the art.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-11, 13, 15, 19, 20, 21, 26, 39-41 have been considered but are unpersuasive.

Applicant asserts the Office fails to show a reasonable expectation of success in combining the teachings of the references. Specifically, applicant asserts the Office bears the burden to produce evidence to show what properties of minoxidil and daidzein enable the efficacy of both oral and optical administration and how chemical properties of these compounds are related to the chemical properties of taurine such that a skilled artisan would have recognized the efficacy of taurine. Examiner respectfully disagrees. One of ordinary skill in the art already had the knowledge of the functionality of taurine as a cellular activator for regulating hair cells. Formulation of a drug to various delivery systems would have been well within the ordinary skill in the art. Particularly in this case, oral administration of taurine salt already has been known, as shown by McCarty. Although the degree of the efficacy of the various routes of administration may depend on the dosage form and delivery system of a drug, it would have been obvious that the route of the administration itself does not change the biological effect of the drug in a patient, and discovering an effective dosage amount would have been well within the skill of the art. Particularly in alopecia treatment art, co-administration of the drug in both local and systemic route is already well known, as shown in Kung. Thus, it is obvious that a skilled artisan would have been motivated to administer taurine orally in expectation of successfully treating alopecia or reasonably expected that the oral

administration of taurine salt such as in McCarty would be effective in treating the said symptom.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/
Primary Examiner, Art Unit 1611